UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO: **WAVE 6 CASES**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE CERTAIN OPINIONS OF RALPH ZIPPER, M.D.

Defendants Ethicon, Inc. and Johnson & Johnson (hereinafter "Defendants") submit this memorandum in support of their motion to exclude certain opinions of Ralph Zipper, M.D.

INTRODUCTION

Dr. Zipper has offered expert opinions on Defendants' Prosima, Prolift, and TVT-S devices.[1] Defendants adopt and incorporate by reference the *Daubert* motion filed against Dr. Zipper with respect to his opinions on Prosima and Prolift for Ethicon Wave 1, Dkt. Nos. 2068 (motion), 2072 (memorandum in support), and supporting Reply brief, Dkt. 2221, and the Court's Wave 1 ruling with respect to Dr. Zipper. *See* Order, Dkt. No. 2717; *see also* Dkt. 2418 (Notice of Adoption for Wave 2 Order), 3299 (Notice of Adoption for Wave 3 Order).

[1] Three plaintiffs who were not implanted with any of Defendants' Prosima, Prolift, or TVT-S devices have neverthless designated Dr. Zipper as a general expert in their cases. *See* Exhibit A. These plaintiffs were implanted with TVT, TVT-O, and Gynemesh. Dr. Zipper has not produced *any* expert reports on the TVT, TVT-O, or Gynemesh devices in this Wave, however, and he should therefore be excluded as an expert on these devices for the referenced plaintiffs on this ground alone.

In addition to adopting his previous opinions regarding Prosima and Prolift, Dr. Zipper served a new report in Wave 6 concerning his expert opinions on Defendants' TVT Secur, or TVT-S, device. The present memorandum addresses these new opinions.

Dr. Zipper is a pelvic surgeon and urogynecologist in Florida who has experience in treating pelvic organ prolapse and severe urinary incontinence. *See generally* Exhibit B (Curriculum Vitae). Plaintiff, however, hopes to elicit testimony from Dr. Zipper about topics that are entirely outside his professional education, training, and experience and therefore outside his area of competence. Moreover, his general opinions are unreliable and largely irrelevant.

Specifically, the Court should preclude Dr. Zipper from testifying about the following:

- Alleged design defect opinions concerning mesh degradation, contraction, and extrusion that require biomaterials expertise that Dr. Zipper does not have;
- Alleged design defect opinions that are not supported by application of a reliable methodology;
- Alleged defective warnings contained in the TVT-S Instructions for Use ("IFU") that are outside of his expertise or that are not supported by a reliable methodology;
- "Safer" alternative products whose comparative safety and efficacy have not been quantified;
- Opinions about Ethicon's alleged knowledge, state of mind and bad acts;
- Opinions that amount to nothing more than historical commentary; and
- Opinions that have not been disclosed in his expert reports;

LEGAL ARGUMENT

Ethicon incorporates by reference the standard of review for *Daubert* motions as articulated by the Court in *Edwards v. Ethicon, Inc.*, 2014 WL 3361923, at *1-3 (S.D.W. Va. July 8, 2014). The Supreme Court's decision in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), precludes "engagement of 'expert' witnesses whose intended role is more to argue

the client's cause from the witness stand than to bring the fact-finder specialized knowledge or expertise that would be helpful in resolving the issues of fact presented by the lawsuit." *In re: Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 538 (S.D.N.Y. 2004). Plaintiffs seek to do precisely that through the testimony of Dr. Zipper. While Dr. Zipper may be qualified to render opinions about pelvic surgery, he has no specialized knowledge or expertise that would substantially assist the jury as it relates to other areas.

Dr. Zipper opines that: 1) the TVT-S was defectively designed; 2) there were safer alternative products; 3) the warnings contained in the TVT-S IFUs and other labeling were inadequate; and 4) the Defendants were aware of the undisclosed risks. Each of these opinions is flawed and should be excluded.

I. Dr. Zipper's Opinions That The TVT-S Was Defectively Designed Are Unreliable.

"Expert opinions premised upon speculation and conjecture are insufficient to create a genuine issue of material fact to survive summary judgment." *Dana Corp. v. Am. Standard, Inc.*, 866 F. Supp. 1481, 1499 (N.D. Ind. 1994). An expert's simple *ipse dixit* is insufficient to establish a matter; rather, the expert must explain the basis of his statements to link his conclusions to the facts. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 157 (1999); *Hines v. Wyeth*, 2011 WL 2680842, at *5 (S.D. W. Va. July 8, 2011).

Dr. Zipper opines that TVT-S is defectively designed because its PROLENE mesh "had inadequate pore size, degraded, contracted, lost elasticity, became rigid, and caused a chronic inflammation." Exhibit C, TVT-S Rep. 225. He opines that it has been known for "[d]ecades" that polypropylene mesh "demonstrated a high incidence of severe inflammation, scarring, contraction, and pain." TVT-S Rep. 222. Dr. Zipper also opines that TVT-S's Ethisorb fixation tips are defective because Ethisorb "is a device cleared for use on the human dura . . . [and] was

never cleared for use on other tissue. TVT-S Rep. 223. Dr. Zipper also opines that the TVT-S was defective because the pore size was defective. TVT-S Rep. 222. Additionally, Dr. Zipper states that the method of laser cutting the TVT-S mesh "changed the properties of the PROLENE sling causing more rigidity and less elasticity," as well as problems with "sling tensioning," which resulted in "failed surgery and resurgery" and an "increased complication [in] erosion and dyspareunia." TVT-S Rep. at 234. As further detailed below, Dr. Zipper's opinions regarding these supposed defects are not based on any reliable methodology but are instead mere *ipse dixit*. Moreover, he lacks the requisite expertise to opine regarding certain characteristics of the TVT-S.

1. Dr. Zipper is not qualified to opine on biomaterial properties of mesh.

Dr. Zipper is neither qualified to opine, nor does he have evidence to support, any opinion addressing the biocompatibility characteristics of the mesh used in the TVT-S. Dr. Zipper is not qualified by education, training, or experience to opine on biomaterials science issues, including, without limitation, polypropylene mesh degradation, rigidity, contraction, and porosity. As he previously testified in another mesh case, he does not have "an engineering degree in materials science," nor has he "attend[ed] classes in materials science when in training." *Hammons v. Ethicon, Inc., et al.*, Sept. 26, 2015 Deposition of Ralph Zipper, M.D. ("9/26/15 Dep.") at 209:1-3, attached as Exhibit D. Dr. Zipper has admitted that he is not an expert in biocompatibility issues. Exhibit D, 9/26/15 Dep. at 208:3-4 ("I do not represent myself as an expert in materials science."). He does not have a demonstrated background in polymer chemistry or biochemical or biomechanical engineering, and his disclosed background indicates that he has never performed any bench research with respect to polypropylene. *See* Exhibit B, Zipper Curriculum Vitae. Dr. Zipper previously testified that he has not conducted one study on

the contraction or shrinkage rates of mesh. Exhibit D, 9/26/15 Dep. at 248:9-11. He has never performed a study on mesh degradation. *See id.* at 248:12-14. Dr. Zipper's only basis for his biomaterials opinions comes from his own idiosyncratic physical examination of the mesh as a practicing urogynecologist—not from any testing. His lack of expertise in this area necessarily impacts the permissible scope of his testimony. *See Johnson & Johnson v. Batiste*, 2015 WL 6751063, at *6, *9 (Tex. App.—Dallas Nov. 5, 2015) (argument that mesh degrades was legally insufficient where plaintiff's expert admitted that "there was no evidence as to how much the polypropylene would have to degrade before it caused injury to a patient").

Dr. Zipper has previously testified that he has "worked closely" with engineers in the past to develop a medical device. Exhibit D, 9/26/15 Dep. at 109:17-110:11. Most recently, he testified with respect to his TVT-S opinions that he worked on a single incision sling device, but his testimony demonstrates that his involvement in that development was limited to implanting the device and writing a report, and that he had no involvement in its invention. Exhibit E, 10/27/17 Dep. 42-48; 57:11-12 ("James Browning invented the sling. I just improved it."). But Rule 702 of the Federal Rules of Evidence does not allow a witness to offer scientific, technical, or other specialized knowledge outside of his own area of expertise merely because he has spent time with potential experts in other fields. Indeed, Rule 702 states that "[a] witness who is qualified as an expert" may testify if "*the expert's* scientific, technical, or other specialized knowledge" so qualified him. Fed. R. Civ. P. 702 (emphasis added). Rule 702 does not allow a witness to offer opinions based upon someone else's knowledge, skill, experience, training, or education. The fact that Dr. Zipper has "worked closely" with engineers or written reports based on surgeries does not make him a biomaterials expert.

Despite his lack of specific expertise, Dr. Zipper offers several opinions concerning the biomaterial properties of polypropylene mesh, most of which he simply regurgitates from the literature which he grossly misinterprets:

- "[T]he PROLENE mesh is now well-known not to be inert and the inflammation is not transient. . . . The medical and scientific literature have demonstrated the polypropylene mesh is not only reactive and inflammatory in perpetuity, but it destroys tissue." (TVT-S Rep. at 45).

- "[P]olypropylene is highly reactive causing a chronic inflammatory response and chronic foreign body reaction and degrades following implantation in the human body." (TVT-S Rep. at 45).

- "As noted herein, the transvaginal implantation of polypropylene mesh favors bacterial contamination with resultant potentiating of the PROLENE material defects. The vast majority of transvaginal mesh implants suffer such contamination." (TVT-S Rep. at 178-79).

- "Ethicon taught surgeons that they may put a second TVT-SECUR in a patient who failed the first TVT-SECUR. Women undergoing either a repeat TVT-SECUR procedure or TVT-SECUR and TVT-O procedures have two layers of the defective PROLENE in the same tract. This is a method that increased the mesh load, foreign body load, [and] per unit area of body tissue. As noted elsewhere herein, the foreign body reaction associated with polypropylene mesh is directly responsible for many complications by means of acute and chronic inflammation, fibrosis, and contraction." (TVT-S Rep. at 186).

- "Both the scientific and medical literature (including Ethicon's own investigations) have consistently shown that PROLENE polypropylene is reactive. Indeed, Ethicon's animal studies demonstrated that the material is reactive, causing chronic inflammation and destroying tissue." (TVT-S Rep. at 191).

- "[P]olypropylene mesh is associated with a chronic foreign body reaction. Ethicon's PROLENE was no exception to this rule." (TVT-S Rep. at 195).

In other mesh litigation, this Court has closely scrutinized experts' qualifications to opine about biomaterial properties and such testimony has been limited to experts with extensive biomaterial and biomechanical engineering education and experience. *See In re C.R. Bard, Inc., Pelvic Repair Sys. Liab. Litig.*, 948 F. Supp. 2d 589, 623 (S.W. W. Va. 2013) (allowing physician testimony regarding biomechanical analysis of mesh only after establishing that

physician had two engineering degrees, had practiced as an engineer for twelve years, and had focused on studying biomechanical analysis of pelvic floor structures and the pelvic floor from an engineering perspective for ten years); *id.* at 633 (expressing "concerns about [physician's] qualifications to testify specifically as to the properties of polypropylene" mesh, but allowing testimony only after establishing that physician not only had a biomedical engineering degree, but also routinely evaluated biomaterials, developed new biomaterials and modified existing biomaterials, and had specific experience with polymeric material). In at least one other case, the plaintiff, recognizing the insufficiency of her expert's qualification to opine on biomaterials, simply conceded that her expert would not offer such testimony at trial. *See Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658, 680 (S.D. W. Va. 2014) (upon defendant's challenge to expert doctor's opinions as to "biomaterials, adequate pore size, adequate weight of polypropylene, polypropylene degradation, biocompatibility of polypropylene, medical device design, and marketing," "plaintiffs conceded that Dr. Margolis will not be offering these opinions at trial"). Similarly, in the present case, Dr. Zipper's lack of biomaterials expertise precludes him from testifying about the biomechanical properties of mesh, including mesh degradation and contraction or the effect of mesh on human tissue.

2. Dr. Zipper's opinions are unreliable.

Even if Dr. Zipper were qualified to testify about biomaterial properties of polypropylene mesh—and he is *not*—his opinions concerning degradation, contraction, rigidity, and porosity are not supported by a reliable methodology. In his deposition on TVT-S, Dr. Zipper admitted that he uses a polypropylene mesh retropubic mid-urethral sling and offers it to his patients. Exhibit E, 10/27/17 Dep. at 23:9-25:21 (indicating use of Boston Scientific's or American Medical Systems' mid-urethral sling). He admits that the mesh in Ethicon's TVT retropubic

device is the same mesh that is in the TVT-S device, including pore size. Exhibit E, 10/27/17 Dep. at 32:7-34:3. He admits that the polypropylene mesh retropubic mid-urethral sling can be efficacious to a patient. Exhibit E, 10/27/17 Dep. at 25:22-26:9. He believes that in implanting such a device he is acting ethically and does not deny that offering polypropylene mesh slings to his patients is within the standard of care. Exhibit E, 10/27/17 Dep. at 25:2-28:11. He believes that the material in the polypropylene mesh sling is defective, but is willing to implant the product in his patients. Exhibit E, 10/27/17 Dep. 27:12-29:23.

Dr. Zipper has also admitted that he uses a polypropylene mesh today called Alyte Y in abdominal sacrocolpopexies (repairs of pelvic organ prolapse). March 20, 2016 Deposition of Ralph Zipper, M.D. ("3/20/16 Dep.") at 41:21-42:19, attached as Exhibit F. Dr. Zipper believes that analysis of randomized trials is the highest level of scientific evidence as to the safety of a product, Exhibit F, 3/20/16 Dep. at 152:18-153:8, and criticizes randomized trials of Ethicon's products. Exhibit F, 3/20/16 Dep. at 153:20-221:19.

When it comes to the polypropylene mesh retropubic mid-urethral sling and Alyte Y mesh he uses in his practice, however, Dr. Zipper does not apply the same methodology he applies to Ethicon's products. Despite his criticism of all polypropylene mesh as "universally defective," Exhibit E, 10/27/17 Dep. 31:9-11, in his deposition for the present cases, Dr. Zipper admitted that he offers synthetic mesh retropubic slings to his patients and implants them in his patients even believing that they are defective. He believes he is acting ethically in doing so and does not deny that implanting such slings is within the standard of care. Yet his report is replete with opinions that the TVT-S, which is made of the same mesh, is defective and should never be implanted in the human body. In short, he has not judged the synthetic mesh retropubic slings that he uses by the same standards as Ethicon's mesh.

With respect to Alyte Y, he has admitted that he was not aware of any randomized clinical trials on Alyte Y mesh at the time of clearance or approval by the FDA; could not name any prospective clinical data performed on Alyte Y mesh prior to FDA clearance or approval; admitted that he had not reviewed the regulatory dossier on Alyte Y, including correspondence between C.R. Bard and the FDA regarding Alyte Y, internal memos from Bard, and emails from Bard. Exhibit F, 3/20/16 Dep. at 312:4-321:10. He also admitted that he had not asked Bard for its regulatory file, internal memos, or internal emails related to the Alyte Y mesh. Exhibit F, 3/20/16 Dep. at 321:11-20. Dr. Zipper also has not judged Alyte Y mesh by the same standards as he judges Ethicon's mesh.

The Court has noted that "an expert's formulation of his or her opinion for the purposes of litigation does not, by itself, justify that expert's exclusion." *Sanchez v. Boston Sci. Corp*., No. 2:12-CV-05762, 2014 WL 4851989, at *4 (S.D. W. Va. Sept. 29, 2014) *reconsideration denied*, No. 2:12-CV-05762, 2014 WL 5320559 (S.D. W. Va. Oct. 17, 2014). The Court cautioned, however, that this concern "does have a role in applying *Daubert*" in that the Court considers "whether experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying." *Id*. (citing *Hoffman v. Monsanto Co.*, No. 2:05–CV–00418, 2007 WL 2984692, at *3 (S.D. W. Va. Oct. 11, 2007)). The Court concluded that it "will not exclude an expert on the sole basis that the opinion arose during litigation, so long as it is otherwise reliable," but "will consider the independence of an expert's testimony as evidence that his 'research comports with the dictates of good science.'" *Id*. (citing *Daubert II*, 43 F.3d at 1317).

Indeed, Rule 702 of the Federal Rules of Evidence requires that an expert's testimony be "the product of reliable principles and methods" and that the expert "reliably appl[y] the principles and methods to the facts of the case." Fed. R. Evid. 702(c), (d). Dr. Zipper's methodology here shifts violently when he is not using a product he has been paid to render an opinion on. The Court should exclude his opinions regarding TVT-S due to this unreliable methodology. *See Sanchez*, 2014 WL 4851989, at *4; *Bethune v. Bos. Sci. Corp.*, 2016 WL 2983697, at *11 (S.D. W. Va. May 20, 2016) (excluding Dr. Blaivas's opinion that polypropylene mid-urethral slings are not safe in the treatment of SUI because "Dr. Blaivas applied standards different than those he applies in his medical practice"); *Mathison v. Bos. Sci. Corp.*, 2015 WL 2124991, at *10-11 (S.D. W. Va. May 6, 2015); *see also In re Zyprexa Prods. Liab. Litig.*, No. 04–MD–1596, 2009 WL 1357236, at *3 (E.D.N.Y. May 12, 2009) (excluding expert's testimony where he had not applied principles and methods reliably to the facts of the case and had "been shockingly careless about the facts in the cases he proposes to opine about: whether weight gain preceded or followed use of Zyprexa").

Further, Courts routinely exclude opinions under *Daubert* where the experts inappropriately extrapolate far beyond the data as Dr. Zipper does here. *See, e.g., Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) (noting that neither "*Daubert* [n]or the Federal Rules of Evidence requires [sic] a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert"). Regarding alleged mesh degradation, the polypropylene used in Defendants' products has special antioxidants to resist degradation, and there is no reliable evidence that degradation occurs inside the human body, let alone that any degradation ever caused clinical harm to anyone. Because Dr. Zipper's opinions have no basis

other than his *ipse dixit*, the Court should exclude his opinions concerning the purported effect of degradation. *See, e.g.*, *Gen. Elec. Co.*, 522 U.S. at 146.

II. Dr. Zipper's Opinion That There Were Safer Alternative Products Is Subjective And Not Supported By Sufficient Facts Or Data.

Expert testimony is only admissible under Rule 702 if it is "based upon sufficient facts or data"—*i.e.*, if it "rests on a reliable foundation." See *Huskey*, 29 F. Supp. 3d at 701 (citing Rule 702 and *Daubert*, 509 U.S. at 597).

In the present case, Dr. Zipper opines that there were a number of other alternative products or techniques that were equally effective to treat stress urinary incontinence than the TVT-S. In particular, he opines that "natural tissue, native tissue surgery is more likely than not safer and better in the long run, if not in the short run," Exhibit E, 10/27/17 Dep. 64:19-65:21, and that a "safer alternative" to PROLENE was a lightweight, large pore mesh called Ultrapro. Exhibit C, TVT-S Rep. at 251; Exhibit E, 10/27/17 Dep. 81:16-82:10. He also opines that a "sutured device" such as the Burch procedure, conventional slings, and midurethral slings, is a safer alternative design. Exhibit E, 10/27/17 Dep. 97:12-98:8

As an initial matter, alternative surgeries that do not use the product at issue in any manner do not satisfy plaintiffs' burden of establishing a safer alternative design, and are therefore irrelevant and unhelpful to the jury. By its very nature, a safer alternative must be another product. Native tissue surgeries and the Burch procedure are not products. As this Court has stated:

> [A]n "alternative design must not be an altogether essentially different product." *Torkie*, 739 F.Supp. 2d at 900. Stated differently, "an alternative design is not reasonable if it alters a fundamental and necessary characteristic of the product." *Id.; see also Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 385 (Tex.1995) (noting, in design defect context, that "[a] motorcycle could be made safer by adding two additional wheels and a cab, but then it is no longer a motorcycle."); *Kimball v. RJ Reynolds Tobacco Co.*, No. C03–664, 2006 WL 1148506, *3 (W.D.Wash.

> Apr. 26, 2006) (holding that a plaintiff "cannot point to an entirely different product as an alternative design").

Hines v. Wyeth, 2011 WL 1990496, at *8 (S.D. W. Va. May 23, 2011); *see also Carlson v. Boston Scientific Corp*., No. 2:13–cv–05475, 2015 WL 1931311, at *7 (S.D.W. Va. Apr. 28, 2015) (excluding expert testimony "that the Burch procedure is more effective than polypropylene mesh slings" because it was not supported by "appropriate validation" and rested solely upon the expert's personal observations); *accord Caterpillar, Inc.*, 911 S.W.2d at 385 (finding that the law of product liability does not "impose liability in such a way as to eliminate whole categories of useful products from the market"). Although in *Hines*, the Court indicated that this presented a jury question, here no reasonable mind could conclude that traditional surgical approaches are *products*.

The notion that the traditional surgical procedures are safer alternatives to Ethicon's products is premised on the assumption that all mesh products are unsafe. Such an "argument . . . really takes issue with the choice of treatment made by [the patient]'s physician, not with a specific fault of" the device. *Theriot v. Danek Med., Inc.*, 168 F.3d 253, 255 (5th. Cir. 1999) (surgical alternative to pedicle screw could not be considered). As explained in *Schmidt v. C.R. Bard, Inc.*, 2013 WL 3802804, at *2 (D. Nev. July 22, 2013), "non-mesh repair is not an alternative design and does not meet Plaintiff's burden to support" a design-defect claim. *See also Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 385 (Tex. 1995) (noting in design defect context that "[a] motorcycle could be made safer by adding two additional wheels and a cab, but then it is no longer a motorcycle" and that product liability law does not "impose liability in such a way as to eliminate whole categories of useful products from the market").

Additionally, Dr. Zipper has no basis to support his conclusions regarding safety and efficacy. He did not disclose any testing, calculations, engineering analysis, or publications that

supported his opinion. *See Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, Order, at 16 (S.D. W. Va. Nov. 20, 2014) (excluding expert opinion of Dr. Uwe Klinge regarding safer alternative design where, "[i]n the section of his report specifically addressing alternative design, Dr. Klinge fail[ed] to cite *any* peer-reviewed studies") (emphasis in original) (attached hereto as Exhibit G). The first *Daubert* factor is whether the theory or technique employed by the expert can be and has been tested. *Daubert*, 509 U.S. at 591-95; *see Watkins v. Telsmith, Inc.*, 121 F.3d 984, 992 (5th Cir. 1997) (proposing alternative design requires more than "conceptualizing possibilities"); *see also Oglesby v. Gen. Motors Corp.*, 190 F.3d 244 (4th Cir. 1999) (affirming exclusion of mechanical engineer's expert testimony where "he did not know the type or composition of the plastic" at issue, failed to ask the manufacturer, analyze or test the part, and did not apply any calculations). Dr. Zipper has failed to satisfy that factor here with respect to safer alternative designs. Although he points to other mesh products that currently exist for different indications, this does not obviate the need for testing of the supposedly safer alternative products. *See Johnson v. Manitowoc Boom Trucks, Inc.*, 406 F. Supp. 2d 852, 860-62 (M.D. Tenn. 2005) ("The plaintiff argues that testing is not required because Mr. Friend's proposed alternative design is already in the marketplace. . . . However, the existence of interlock systems is not at issue in consideration of this prong of the *Daubert* factors. The question is whether Mr. Friend's proposed opinion that the Manitowoc boom truck crane was defectively designed because it lacked such a system is sufficiently reliable that it should be admitted in this case. [Plaintiff's evidence of other devices with interlock systems], even if admissible and proved to be true, does not alter the fact that Mr. Friend did not engage in any testing of his theory.").

Dr. Zipper's testimony does not link his conclusions to the analysis, if any, that he performed to determine that a device made of Ultrapro is indeed safer. Indeed, he testified that,

had the TVT-S been made of Ultrapro, it would still be a defective product. Exhibit E, 10/27/17 Dep. 80:10-12. Quite simply, Dr. Zipper should not be permitted to suggest that other mesh products offer a safer alternative given that he is unwilling to stand behind the alternative and confirm that it is safe and effective in treating SUI. In *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 712-13 (S.D. W. Va. 2014), another expert, Dr. Abhay Pandit, wished to offer vague, noncommittal testimony concerning how the mesh in TVT-O could be improved and suggesting that laser cut mesh was preferable. This Court precluded Dr. Pandit from offering these opinions because they were unreliable and because Dr. Pandit was unable to offer such opinions within a reasonable degree of medical certainty. *Id.* That same reasoning applies here. Therefore, Dr. Zipper's opinion that safer alternative products exist is unreliable and should be excluded.

III. This Court Should Exclude Dr. Zipper's Opinions Regarding The Adequacy Of The TVT-S IFU.

Dr. Zipper contends that the IFU that accompanied the TVT-S were defective and failed to provide adequate warnings and information to treating surgeons. Exhibit C, TVT-S Rep. at 38-39; 50-51; 156-75; 196-97. Dr. Zipper has insufficient expertise in developing warnings-related documents. His curriculum vitae and prior depositions testimony reveal insufficient experience in preparing a medical device IFU and no training concerning FDA regulations related to developing warnings or labeling. Indeed, this Court has previously recognized that "Dr. Zipper does not possess the additional expertise to offer expert testimony about what an IFU should or should not include." *In re. Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4944991, --- F. Supp. 3d --- (S.D. W. Va. Sept. 1, 2016) (order excluding certain general warnings opinions of Dr. Zipper).

Ethicon has previously acknowledged that this Court has ruled in prior proceedings that a urogynecologist may testify "about the specific risks of implanting mesh and whether those risks

appeared on the relevant IFU." *See, e.g., In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4536885, at *2 (S.D. W. Va. Aug. 30, 2016). However, Dr. Zipper does not limit his opinions to whether risks were included in the IFU. Instead, he criticizes Ethicon for allegedly not including in the IFU certain methods for insertion of that device (Exhibit C, TVT-S Rep. at 160-61); not including in the IFU opinions of alleged Ethicon key opinion leaders (Exhibit C, TVT-S Rep. at 162-63); not including in the IFU alleged situations in which implant removal may be required (Exhibit C, TVT-S Rep. at 167); not including in the IFU "instruction for managing . . . adverse reactions . . . warning of the risk of inability to remove the device in its entirety . . . a discussion of uncertainties and differing opinions . . . the entirety of human safety and efficacy data at the time of product launch . . . [or] qualif[ication] or quantif[ication] [of the] risks." (Exhibit C, TVT-S Rep. at 196).

Dr. Zipper has no expertise in labeling that qualifies him to fault Ethicon for supposedly failing to include everything under the sun in its IFU. Dr. Zipper initially admitted in previous deposition testimony that he did not "hold [himself] out as a regulatory expert." Exhibit D, 9/26/15 Dep. Tr. 229:14. He later testified that he had become an expert in recent years—essentially in the course of this litigation—an argument which held no water.[2] *See* Exhibit F, 3/20/16 Dep. at 240:9-22; 246:9-16; 249:13-253:17. Now, in his deposition for the TVT-S, Dr. Zipper testified that in his role as CEO of two medical device companies making products unrelated to TVT-S or the condition it treats, he is "intimately involved in the creation of labels." Exhibit E, 10/27/17 Dep. at 94:25-95:13. He does not describe what he means by "intimately." Examination of his testimony reveals that he is still unqualified to testify about the

[2] Dr. Zipper cannot become an expert on FDA labeling simply by virtue of litigation. Consultation in litigation hardly equates to meaningful training or hands-on experience in regulatory warning requirements. *See In re Air Crash Disaster*, 795 F.2d 1230, 1234 (5th Cir. 1986) (expressing skepticism of experience gained by expert through litigation consulting).

TVT-S IFU: he testified that, for his dissimilar products, "we are submitting a sub Q application for both an IDE and randomized control trials for new indications of use and those applications are associated with new labels and *I'm in the process of writing those labels.*" Exhibit E, 10/27/17 Dep. at 95:9-15 (emphasis added). In other words, neither of the products even has a finished warning label.

Dr. Zipper may be attempting the initial stages of drafting labels recently, but he has not once seen the IFU process through to completion and cannot show that either of his drafts have been or will be approved. It is a stretch to see how present involvement in his first ever experience with the IFU process is sufficient to label him an "expert" in the development of warning labels. As such, he cannot assert any expertise in the area. Plaintiffs' argument must fail and Dr. Zipper's warning opinions beyond those made as a urogynecologist should be excluded. *See Cisson v. C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013) (excluding plaintiff's expert, Dr. Bob Shull, on warnings and labels for medical devices: "Despite his stellar qualifications as a urogynecologist, Dr. Shull is unqualified to testify on the specific issue of product warnings, as evidenced by his lack of familiarity with the process"); *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 550-51 (S.D. W. Va. 2014), *as amended* (Oct. 29, 2014) (holding that urogynecologist Dr. Donald Ostergard, although qualified to opine about design of sling in question, was not qualified to opine on product warnings and FDA compliance). Because Dr. Zipper is not qualified to opine about the adequacy of the warnings at issue here, the Court should exclude his testimony about that subject.

Additionally, Dr. Zipper opines that Ethicon's labeling failed to warn of "acute and chronic groin pain, leg pain, dyspareunia, recurrent urinary tract infections, chronic erosion, vaginal dysbiosis, the signs and symptoms of such adverse events, and instructions for managing

such adverse reactions." Exhibit C, TVT-S Rep. at 195-96. But in his deposition, he admitted that the risk of mesh erosion from a synthetic sling was commonly known within the relevant medical community, and that erosion is a potential complication of any polypropylene mesh sling. Exhibit E, 10//27/17 Dep. 54:11-55:15; 57:18-22. He also admitted that the risk of dyspareunia as a potential complication was commonly known by pelvic floor surgeons, and that dyspareunia was a potential risk of a sling that he himself had developed. Exhibit E, 10/27/17 Dep. 56:3-60:6. He admitted that incontinence surgery is associated with the risk of dyspareunia. Exhibit E, 10/27/17 Dep. 61:16-17. He also admitted that there is no such thing as a risk-free surgery. Exhibit E, 10/27/17 Dep. 66:2-4. Dr. Zipper has failed to explain why the IFU should warn of complications that were commonly known in the relevant medical community. His opinions are unreliable and should be excluded.

IV. The Court Should Exclude Dr. Zipper's Opinions About Ethicon's Knowledge, State of Mind and Alleged Bad Acts.

The Court should preclude Dr. Zipper from testifying about Ethicon's alleged knowledge and bad acts. Dr. Zipper's reports are rife with statements as to what Ethicon allegedly knew or allegedly did with an alleged state of mind. For instance, Dr. Zipper states that "Ethicon was aware that it had not demonstrated safety and efficacy prior to commercialization of its experimental TVT-SECUR device and intended to commercialize the experimental TVT-SECUR device without such demonstration." Exhibit C, TVT-S Rep. 43. He also states that "Ethicon was "aware of the defectiveness of the design and . . . chose not to change the design secondary to financial consideration includ[ing] those of patent production and developing costs." Exhibit C, TVT-S Rep. 237; *see also id.* at 61, 68, 70, 77, 122, 142, 144, 146, 164, 172, 190, 203, 217, 224-25, 233, 236-37, 240, 250, 229. Dr. Zipper opines repeatedly on Ethicon's alleged state of mind in his TVT-S report, stating, for example, that "Ethicon knowingly omitted

from its TVT-SECUR device a plastic sheathing it believed could decrease bacterial contamination." Exhibit C, TVT-S Rep. 180; *see also id.* at 48, 54, 65-66, 77, 80, 122, 146, 152-53, 176, 187, 190. For the same reasons set forth in Ethicon's Wave 1 motion addressing Prosima and Prolift opinions, this Court should exclude these same types of opinions as related to Dr. Zipper's TVT-S testimony. *See* Dkt. 2072 at PageID #: 45658-45660; Dkt. 2221 at PageID #: 69956; Dkt. 2717, Memorandum Opinion and Order (*Daubert* Motion re: Ralph Zipper, M.D.) (excluding Dr. Zipper's state-of-mind and legal-conclusion expert testimony).

V. The Court Should Exclude Dr. Zipper's Opinions That Amount to a Mere Historical Commentary.

The vast majority of Dr. Zipper's reports consists of cumulative historic commentary about Defendants' alleged bad acts—opinions that are improper because they have nothing to do with his expertise. As this Court has noted, such a rehashing of a fact narrative is improper. *Hines v. Wyeth*, 2011 WL 2680842, at *5 (S.D. W. Va. 2011) (Copenhaver, J.) (excluding expert testimony in part because it "merely regurgitates factual information that is better presented directly to the jury rather than through the testimony of an expert witness").

Such improper testimony includes Dr. Zipper's opinions about Defendants' alleged knowledge, state of mind, and product warnings, which the Court should also exclude for the reasons set forth above. Other examples of opinions beyond Dr. Zipper's expertise that amount to an impermissible historical commentary include the regurgitation of factual timelines on pages 19-43 and 49-80 of his TVT-S report. For the same reasons set forth in Ethicon's Wave 1 motion addressing Prosima and Prolift opinions, this Court should exclude these same types of opinions as related to Dr. Zipper's TVT-S testimony. Dkt. 2072 at PageID #: 45660-45661; Dkt. 2717, Memorandum Opinion and Order (*Daubert* Motion re: Ralph Zipper, M.D.) (excluding Dr. Zipper's parroting facts found in corporate documents).

VI. The Court Should Preclude Dr. Zipper from Rendering Any Other Opinions That Are Not Disclosed.

Finally, the Court should preclude Dr. Zipper from rendering opinions that are not set forth in his expert reports and/or that are not supported by information disclosed in his reliance list included with his expert report. As he showed in his deposition on his general opinions on TVT-S, he does not feel so confined. *See* Exhibit E, 10/27/17 Dep. 10:22-11:25. Under Fed. R. Evid. 26(a)(2)(B), an expert report must contain "a complete statement of all opinions the witness will express and the basis and reasons for them," as well as "the facts or data considered by the witness in forming them." (emphasis added). Thus, Plaintiffs may not elicit opinions from Dr. Zipper that are not included in his report.

CONCLUSION

For the reasons set forth above, the Court should limit the parameters of Dr. Zipper's testimony consistent with the foregoing.

Respectfully submitted,

ETHICON, INC. AND
JOHNSON & JOHNSON

/s/ David B. Thomas
David B. Thomas (W. Va. Bar No. 3731)
Thomas Combs & Spann, PLLC
300 Summers Street, Suite 1380
P.O. Box 3824
Charleston, WV 23558-3824
(304) 414-1800

/s/ Christy D. Jones
Christy D. Jones
Butler Snow LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
(601) 985-4523

CERTIFICATE OF SERVICE

I certify that on this date, I electronically filed this document with the Clerk of the Court using the CM/ECF system which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones
Christy D. Jones

39408614.v1